

REMARKS:

Applicant has carefully studied the Non-Final Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 1, 3-8, 10-11, 14-16 and 19-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over by U.S. Patent No. 5,968,006 to Hofmann.

With respect to claim 1, the Office states that Hofmann discloses a method an apparatus for electromanipulation of chemical species in vivo to a target tissue (abstract) comprising: a substantially planar nonconductive sheet (20, 22) conformable to the three dimensional topography of the surface of the target tissue (column 4, lines 65-67); a plurality of electrode elements secured in spaced apart relation on the array base (figure 1A), the electrode elements adapted to be coupled to a voltage controlled and current controlled electrical source (column 4, lines 24-56). The Office further states that Hofmann teaches that the electrodes are spaced in a manner so that sufficient voltage for permeation can be applied without inducing high voltage deeply in the underlying target (column 4, lines 52-56), and that it would have been obvious to one having ordinary skill in the art to vary the spacing of the electrodes to obtain the desired power or voltage since it has been held that discovering an optimum value of a result effective variable involved only routine skill in the art.

Claim 1 has been amended to more clearly describe that which the Applicant regards as the invention.

Amended claim 1 recites, a device for electromanipulation of chemical species in vivo relative to a target tissue comprising: a voltage controlled and current controlled electrical

source; a substantially planar nonconductive sheet conformable to the three-dimensional topography of the surface of the target tissue; and a plurality of electrode elements secured in spaced apart relation on the sheet, the electrode elements coupled to receive a voltage controlled and current controlled output from the electrical source, the voltage controlled and current controlled output from the electrical source being such that when the electrode elements are positioned on the surface of the target tissue and a controlled voltage is applied between the electrode elements, a current drawn by the electrode elements is controlled by the electrical source to insure that a peak power of less than about 1 kilowatt is delivered to the target tissue.

As such, in accordance with claim 1, the voltage controlled and current controlled electrical source is used to apply a controlled voltage across the electrodes and when the electrodes are placed in contact with the target tissue, the electrical source controls the current that is drawn by the electrodes such that the power delivered to the target tissue is less than 1kW.

It is known that the electrical resistance of a target tissue varies based on the unique characteristics of the tissue. Additionally, the resistance between any two electrodes varies as the distance between the electrodes varies. Accordingly, in a typical electroporation system such as that described by Hofmann, when a voltage is applied between any two electrodes to establish a desired electric field, the current drawn by the electrodes from the electrical source is not limited and the current necessary to establish the desired electric field is drawn regardless of the power level that results due to the characteristics of the tissue and the electrode positioning. In other words, Hofmann does not describe a system whereby the voltage and the current are controlled to insure that a peak power of less than 1kW is delivered to the tissue. In contrast, in Hofmann, the voltage is applied and the current necessary to establish the desired electric field is drawn by the electrodes, regardless of the power level necessary to establish the electric field.

In addition, Applicant contends that Hofmann does not teach “a voltage controlled and a current controlled electrical source” as described and claimed by the present invention.

The Office states that Hofmann teaches such a source at column 4, lines 24-56.

Applicant respectfully disagrees with the Office. Hofmann teaches an electroporation power supply **16**, and an iontophoresis power supply **18** at column 4, lines 24-56. However,

neither of these power supplies is described as being capable of controlling the voltage and the current to a load. As such, Hofmann does not teach controlling the current drawn by the electrode assembly, but merely describes establishing an electric field between the electrodes by applying a voltage to a tissue in which a tissue resistance has been previously determined by investigation (col. 6, lines 11-15).

Accordingly, Applicant contends that claim 1 is patentable over Hofmann because Hofmann does not teach all the elements of claim 1, including the claim element which recites “the voltage controlled and current controlled output from the electrical source being such that when the electrode elements are positioned on the surface of the target tissue and a controlled voltage is applied between the electrode elements, a current drawn by the electrode elements is controlled by the electrical source to insure that a peak power of less than about 1 kilowatt is delivered to the target tissue”.

For the reasons presented above, amended independent claim 1 is patentable over Hofmann and is believed to be in condition for allowance.

Claims 3-8, 10-11 and 14-16 and 19-22 are dependent upon claim 1, which has been shown to be allowable, and are therefore allowable as a matter of law.

Independent claim 23 has been amended to more clearly describe that which the Applicant regards as the invention.

For the reasons present above regarding the patentability of independent claim 1, Applicant contends that amended independent claim 23 is patentable over Hofmann and is believed to be in condition for allowance.

Independent claim 24 has been amended to more clearly describe that which the Applicant regards as the invention.

For the reasons present above regarding the patentability of independent claim 1, Applicant contends that amended independent claim 24 is patentable over Hofmann and is believed to be in condition for allowance

Claims 25-28 are dependent upon claim 24, which has been shown to be allowable, and are therefore allowable as a matter of law.

Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hofmann (U.S. 5, 318,514) in view of Eppstein et al. (U.S. 2004/0039343).

Claims 17 and 18 are dependent upon claim 1, which has been shown to be allowable over Hofmann. As such, Hofmann in combination with Eppstein et al. does not teach all the elements of claims 17 and 18. Accordingly, claims 17 and 18 are believed to be in condition for allowance.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,
SMITH & HOPEN

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CERTIFICATE OF ELECTRONIC TRANSMISSION

(37 C.F.R. 2.190 (b))

I HEREBY CERTIFY that this Preliminary Amendment is being electronically transmitted to the Patent and Trademark Office through EFS Web on June 19, 2009.

Date: June 19, 2009

/terri l todd/

Terri L. Todd